**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF TEXAS**
**HOUSTON DIVISION**

| | | |
|---|---|---|
| UNITED STATES OF AMERICA ex rel. John King and Jane Doe, et al., | § | |
| *Plaintiffs,* | § | |
| vs. | § | CIVIL ACTION NO. 06-2662 |
| SOLVAY S.A., et al., | § | |
| *Defendants.* | § | |

**DEFENDANT SOLVAY PHARMACEUTICALS, INC.'S MEMORANDUM IN SUPPORT OF ITS RENEWED MOTION FOR PARTIAL SUMMARY JUDGMENT ON RELATORS' P&T-COMMITTEE-INFLUENCE THEORY**

Jonathan L. Diesenhaus (pro hac vice)
Jessica L. Ellsworth (pro hac vice)
555 Thirteenth Street, NW
Washington, DC 20004
Tel.: (202) 637-5600
Fax: (202) 637-5910
jonathan.diesenhaus@hoganlovells.com
jessica.ellsworth@hoganlovells.com

Bruce D. Oakley
Texas Bar No. 15156900
Southern District No. 60627
HOGAN LOVELLS US LLP
700 Louisiana Street, Suite 4300
Houston, Texas 77002
Tel.: (713) 632-1435
Fax: (713) 583-8909
bruce.oakley@hoganlovells.com

**ATTORNEY-IN-CHARGE FOR ABBVIE PRODUCTS, LLC, f/k/a SOLVAY PHARMACEUTICAL, INC.**

# TABLE OF CONTENTS

**Page**

# TABLE OF AUTHORITIES

**Page(s)**

**CASES**



**STATUTES**

**RULE:**



**OTHER AUTHORITIES**

## INTRODUCTION

Solvay Pharmaceuticals, Inc. ("SPI")[1] is entitled to summary judgment on Relators' theory that SPI caused the submission of false claims to Medicaid programs around the country from 1997-2007 by "wooing" members of state Pharmacy and Therapeutic (P&T") committees to obtain a preferred status for Aceon, AndroGel, or Luvox on a preferred drug list ("PDL") or those drugs' inclusion in a Medicaid formulary. At the motion-to-dismiss stage, the Court held that this theory is one of two "alternative" ways that Relators had plausibly pled they could demonstrate the falsity of claims that were, on their face, for reimbursable uses of Aceon, AndroGel, and Luvox. Unlike at the pleading standard, Relators can only survive summary judgment if they have evidence that the purported "wooing" actually resulted in SPI's drugs receiving a preferred listing or being added to a formulary and, if so, that claims for non-reimbursable prescriptions were submitted and paid as a result. As detailed below, Relators cannot meet that test. Their theory is based on a misunderstanding of the impact of a PDL listing. And in any event, there is no evidence that Luvox was ever listed as preferred on a PDL in any state in any time period, and there are only fourteen states where either Aceon or AndroGel were listed as preferred on a PDL for any period of time. At a minimum, SPI is entitled to summary judgment on Relators' theory as to all of the states and time periods in which this evidence is lacking.

The Medicaid statute limits the discretion of states to exclude or restrict coverage for outpatient prescription drugs. One permissible mechanism for doing so is that a state may limit coverage to only "medically accepted indication[s]" of drugs. 42 U.S.C. § 1396r-8(d)(1)(B)(i). Solvay pointed out in its motion to dismiss that claims for medically accepted indications are not

[1] SPI is now known as AbbVie Products, LLC.

"false claims," because those claims were for uses of the drugs the statute required the state to pay for, and the Court agreed. Dkt. 153, Order at 55 ("[C]laims for payment of medically accepted indications are not false claims."). The Court went on to accept, however, Relators' argument that they had plausibly pled two "alternative" ways in which claims submitted for medically accepted indications could still be actionable as "false claims." Id. at 62. Relators' first theory was that SPI had defrauded the compendia DrugDex into listing "support" for certain uses, which affected whether those uses were considered medically acceptable and required to be paid. That theory will be dealt with in a separate motion for partial summary judgment when discovery is complete. Relators' second theory was that SPI had "wooed" states' P&T committee members to obtain a favorable status on formularies and PDLs, and thereby caused states to view Medicaid claims as payable that would not have otherwise been payable. Id. at 62-64. The Medicaid statute indicates that if a state meets the statutory requirements for a Medicaid formulary, the state can exclude coverage of even medically accepted indications from its Medicaid program. 42 U.S.C. § 1396r-8(d)(1)(B)(iv). The Medicaid statute also permits states to impose prior authorization requirements, and PDLs are one means of doing so.

Relators cannot survive summary judgment because their legal theory depends on a preferred PDL listing affecting whether Medicaid covers off-label uses of drugs. Preferred status on a PDL, however, does no such thing. The mere fact that a drug is listed as preferred on a PDL does not transform any claim for an otherwise non-payable use into a claim for a payable one. In contrast to the impact of a DrugDex listing, states do not use "preferred" PDL listings to determine whether their Medicaid programs covers particular uses of a drug. "Preferred" status has an entirely different function: Drugs listed as "preferred" on PDLs do not require prior authorization; drugs that are not listed or are listed as "not preferred" generally require prior

authorization. Rather than impact whether claims for particular uses of a drug are reimbursable, preferred status serves a gatekeeping function that is largely designed to encourage physicians to prescribe generic drugs and drugs for which brand drug manufacturers give discounts to the state. As the Court has recognized, states could "require prior authorization or have preferred drug lists to control against prescriptions for uses that are not medically indicated." Dkt. 153, Order at 8 n.10. But under the Medicaid statute, those listings would not, in and off themselves, render reimbursable an otherwise non-reimbursable use of a prescription drug.

In addition to this legal stumbling block, Relators' P&T-committee-influence theory also falls apart because they lack evidence to support it. Prevailing on the theory would require evidence demonstrating that SPI's drugs in fact received a preferred listing on a PDL or were included in a state's formulary. After months of additional discovery and multiple rounds of briefing, this motion details the many ways in which this evidence to support this theory is largely nonexistent. Finally, since no state has followed the roadmap for adopting a Medicaid formulary, Relators cannot show that any of the three drugs at issue could be listed on one. Regardless of any "wooing" Relators would argue shows that SPI worked to curry favor with a state's P&T committee members, the evidence shows that for most states and most time periods, Relators cannot establish that the "wooing" resulted in any "preferred" status for the drugs.

Faced with these factual and legal deficiencies, Relators' defense of their allegations has been to launch an aggressive campaign of diversion – an extensive argument in support of a radical new interpretation and expansion of their claims beyond the bounds of their already expansive Fifth Amended Complaint. See Dkt. 286, Amended Response. It is far too late for such a volte-face. Relators are limited to the theory they pled—not some broader theory that they may wish they had pled. Cf. Dkt. 227, Order at 9 ("Relators have not shown good cause for

amending the scheduling order."). SPI is entitled to summary judgment on Relators' theory that SPI caused the submission of false claims by improperly targeting state P&T committee members to obtain preferential placement on PDLs and inclusion in Medicaid formularies.

**SUMMARY JUDGMENT EVIDENCE**

SPI submits the following summary judgment evidence in support of its Motion:

| | |
|---|---|
| Exhibit 1. | Aceon Label (2003) |
| Exhibit 2. | Aceon Revised Label (2005) |
| Exhibit 3. | AndroGel Label (2000) |
| Exhibit 4. | Luvox Label (1994) |
| Exhibit 5. | Luvox Revised Label (1997) |
| Exhibit 6. | National Conference of State Legislatures Guidelines on Preferred Drug Lists |
| Exhibit 7. | Letter from Dennis G. Smith, Director of Center for Medicaid and State Operations, Centers for Medicare and Medicaid Services, to State Medicaid Directors (Sept. 18, 2002) |
| Exhibit 8. | PDL Summary Chart |
| Exhibit 9. | Declaration of Dianne Chambers |
| Exhibit 10. | Declaration of Matthew Iaconetti |
| Exs. 11-625. | PDLs from various states |
| Exs. 626-638. | Email correspondence from various states |
| Exhibit 639. | Declaration of Briana Black |
| Exhibit 640. | Colorado Medicaid PDL Program Annual Report, Jan. 1, 2008 – Dec. 31, 2008, available at http://www2.cde.state.co.us/artemis/hcpserials/hcp128internet/hcp1282008internet.pdf. |
| Exhibit 641. | Neb. Leg. Bill 83, available at http://www.nebraskalegislature.gov/FloorDocs/100/PDF/Slip/LB830.pdf. |
| Exhibit 642. | N.C. Sess. Law 2009-451, available at http://www.ncleg.net/Sessions/2009/Bills/Senate/PDF/S202v8.pdf. |
| Exhibit 643A. | Excerpt of Medicaid State Plan for Utah, Attachment #12a to Attachment 3.1-A, available at http://health.utah.gov/medicaid/stplan/A_3-01-A.pdf. |
| Exhibit 643B. | State of Utah Medicaid Preferred Drug List report, available at http://health.utah.gov/medicaid/stplan/LegReports/PDL%20Savings_09-08-10.pdf. |
| Exhibit 644. | Excerpt of Medicaid State Plan for Texas, Appendix 1 to Attachment 3.1-A, §12a, available at https://www.hhsc.state.tx.us/medicaid/about/state-plan/docs/BasicStatePlanAttachments.pdf |
| Exhibit 645. | Excerpt of Medicaid State Plan for Tennessee, Attachment 3.1.A.I, § 12.a(3), (10), available at http://www.tn.gov/tenncare/forms/3-1-a.pdf |

Exhibit 646. Letter from CMS to Doug Porter, Washington Health Care Authority (Sept. 25, 2012), available at http://www.hca.wa.gov/medicaid/Documents/CMSRequestForAdditionalInformation.pdf

Exhibit 647. Letter from Washington Health Care Authority to Interested Parties (Apr. 2, 2013), available at http://www.hca.wa.gov/pdp/documents/interested_parties_formulary_040213.pdf

Exhibit 648. Excerpt of Medicaid State Plan for Kentucky, Attachment 3.1-A § 12(a)(1), available at http://chfs.ky.gov/NR/rdonlyres/6877F47E-5764-4DE5-B535-BB2DC6838191/0/KYMedicaidStatePlanAttachment11AAttachment31F.pdf

Exhibit 649. Notice of Intention To Issue A Subpeona Duces Tecum on the New Jersey Department of Human Services dated May 13, 2013

Exhibit 650. South Dakota Request for Information, Medicaid PDL, dated Feb. 10, 2012, available at http://dss.sd.gov/PDLRFIDRAFTFINAL.2.10.pdf

## NATURE AND STAGE OF THE PROCEEDING

This case is in the final stages of fact discovery. Relators filed suit after being terminated from SPI's sales force in 2002 for violating company policy. The Court's motion-to-dismiss ruling (Dkt. 153) held that Relators' FCA allegations based on off-label promotion survived dismissal in three ways: (1) Relators plausibly pled that SPI promoted its drugs off-label to physicians, causing false claims to be submitted to the federal health care programs for uses that were not medically indicated; (2) Relators plausibly pled that SPI defrauded and/or colluded with DrugDex to improperly expand the list of medically accepted indications that are covered by the federal health care programs; and (3) Relators plausibly pled that SPI engaged in improper marketing to members of state P&T committees to obtain formulary- and PDL-listings that rendered its drugs reimbursable under a state's Medicaid program.

The Court declined, at the motion-to-dismiss stage, to address SPI's argument that P&T committees and the PDL lists they authorize do not affect the reimbursable uses of drugs under a

state's Medicaid program. The Court instead invited SPI to reassert this argument at the summary judgment stage. Dkt. 173, Order at 9 (Aug. 29, 2012).

SPI accepted that invitation in a motion it filed on November 20, 2014. Dkt. 232-233. Relators filed an opposition, a Rule 56 motion for additional discovery time, evidentiary objections, and a motion to strike. Dkt. 239-241. The Court granted Relators additional discovery. Dkt. 262. Relators filed an amended response after the completion of that additional discovery on August 29, 2014; that response raised a number of extraneous issues and withdrew their P&T-committee-influence theory in several respects. Dkt. 286. Relators have also withdrawn the vast majority of their previously asserted evidentiary objections. Dkt. 284. The Court then denied SPI's motion without prejudice and directed that the motion be re-filed in the context of this clearer record on or before October 7. Dkt. 298.

## STATEMENT OF FACTS

### A. Drugs at Issue

This case involves three drugs. Aceon is an ACE inhibitor initially approved by FDA in 1993 to treat essential hypertension (high blood pressure). See Ex. 1, Aceon Label (2003). FDA approved the drug for use in treating stable coronary artery disease in 2005. See Ex. 2, Aceon Revised Label (2005). AndroGel is a synthetic testosterone gel approved by FDA in 2000 to treat "males for conditions associated with a deficiency or absence of endogenous testosterone." Ex. 3, AndroGel Label (2000). Luvox is a selective serotonin reuptake inhibitor ("SSRI") that FDA approved in 1994 to treat obsessive compulsive disorder ("OCD") and approved in 1997 to treat OCD in children. See Ex. 4, Luvox Label (1994); Ex. 5, Luvox Revised Label (1997). As Relators' acknowledge, SPI has not promoted or sold Luvox in the United States since May 2002. Dkt. 154, 5th AC ¶ 74.

## B. Prescription Drug Coverage Under Medicaid

### 1. States cannot exclude coverage for "medically accepted indications."

Under federal law, unless an exception applies, states that provide prescription drug coverage under Medicaid must reimburse prescriptions of all "covered outpatient drugs" for all "medically accepted indication[s]." 42 U.S.C. § 1396r-8(d)(1)(B)(i). "Covered outpatient drug[s]" include prescription drugs, such as Aceon, AndroGel, and Luvox. 42 U.S.C. § 1396r-8(k)(2). "Medically accepted indication[s]" include both FDA-approved indications and off-label uses "supported by one or more citations" in DrugDex or two other listed compendia. 42 U.S.C. § 1396r-8(k)(6). As a result, absent an exception, states must cover all uses of prescription drugs that are approved by FDA or supported by at least one of the statutorily identified compendia. The Court's rulings repeatedly recognized this basic construct. Dkt. 153, Order at 55 (recognizing that a claim for an on-label use or a claim for "an off-label use [that] is supported by DRUGDEX or another approved compendia . . . is a 'medically accepted indication,' and claims for payment of medically accepted indications are not false claims"); id. at 57 ("Absent special circumstances, states cannot restrict coverage of a drug if it is used for a medically accepted indication."); id. at 63 (citing statutory provisions requiring coverage for medically accepted indications).

### 2. PDLs are a form of a prior authorization program that some states use to help control against prescriptions for non-medically accepted indications.

Although states may not restrict coverage of medically accepted indications, states can subject covered outpatient drugs to "prior authorization" requirements. 42 U.S.C. § 1396r-8(d)(1)(A), (d)(5). Preferred drug lists, or PDLs, are one method of imposing a prior-authorization requirement. See 78 Fed. Reg. 42,160, 42,223 (July 15, 2013). Many state Medicaid programs have established PDLs to delineate certain drugs as "preferred," which

indicates that they will be reimbursed without the patient obtaining prior authorization, or non-preferred, which indicates that prior authorization is needed. See, e.g., Ex. 6, Richard Cauchi, National Conference of State Legislatures, Pharmaceutical Preferred Drug Lists (PDLs) – State Medicaid and Beyond (2007) ("NCSL Guidelines").[2] It follows that states could use PDLs "to control against prescriptions for uses that are not medically indicated." Dkt. 153, Order at 8 n.10.

A state P&T committee, comprised of qualified healthcare professionals, typically advises the state on which drugs in a particular therapeutic class to include on its PDL. 78 Fed. Reg. at 42,223. This committee "reviews evidence-based information . . . [and] comparative clinical trials" involving the drug to assist its decision. Id. See also, e.g., Texas Medicaid/CHIP Vendor Drug Program, available at http://www.txvendordrug.com/pdl/ptcom.shtml ("The Texas Pharmaceutical and Therapeutics (P&T) Committee meets quarterly to develop recommendations for the Preferred Drug List, considering the clinical efficacy, safety, cost-effectiveness, and program benefit associated with drug products."); Utah Department of Health, Medicaid, P&T Committee, available at https://medicaid.utah.gov/pharmacy/pt-committee ("The Pharmacy and Therapeutics (P&T) Committee provides recommendations for the Medicaid Preferred Drug List (PDL)").

Very few states adopted PDLs prior to 2002. In September 2002, however, CMS wrote to state Medicaid directors to endorse PDLs as a means to encourage drug manufacturers to enter into "supplemental rebate agreements" with states for covered outpatient drugs purchased by Medicaid recipients. See Ex. 7, Letter from Dennis G. Smith, Director of Center for Medicaid

[2] The name and form of these lists vary by state. See Ex. 6, NCSL Guidelines at 1 ("Not all states use the term 'PDL,' and the extent of coverage, the process for inclusion and approval, and the enforcement mechanisms vary substantially in some cases.").

and State Operations, Centers for Medicare and Medicaid Services, to State Medicaid Directors (Sept. 18, 2002) ("State Medicaid Letter"); 42 U.S.C. § 1396r-8(d)(5). Essentially, in this sort of agreement, a manufacturer agrees to pay a state program rebates (i.e., discounts) based on the volume of its drugs used to treat the state's Medicaid population. See id. To assist states in negotiating these manufacturer discounts, CMS explained that states may establish PDLs and assign a "non-preferred status" to drugs that are not subject to a supplemental rebate agreement with the manufacturer. See id. Following CMS's guidance, many states had implemented PDLs by 2007. See Ex. 6, NCSL Guidelines at 1.

PDLs, like other vehicles states enforce through prior authorization requirements, do not change the obligation of state Medicaid programs to reimburse all "medically accepted indications" of "covered outpatient drugs," regardless of whether a particular drug has "preferred" (no prior authorization required) or "non-preferred" (prior authorization required) status on a state's PDL. 42 U.S.C. § 1396r-8(d)(1)(A), (d)(5).

**3. PDLs and prior authorization are distinct from Medicaid formularies.**

In 1993, Congress amended the Medicaid statute "to allow the States to use formularies subject to strict limitations." Pharmaceutical Research & Mfrs. of Am. v. Walsh, 538 U.S. 644, 653 (2003); see 42 U.S.C. § 1396r-8(d)(1)(B)(iv) (listing as a "[p]ermissible restriction" on the coverage of drugs that "the State has excluded coverage of the drug from its formulary established in accordance with paragraph (4)"). The statute spells out five criteria for establishing a Medicaid formulary, including that a state can exclude a drug "only if" the drug "does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion." Id. § 1396r-8(d)(4). Significantly, the provision specifies that a prior

authorization program, which is permitted under a separate paragraph, "is not a formulary subject to the requirements of this paragraph." Id. § 1396r-8(d)(4).

The Medicaid statute thus makes clear that "a prior authorization program and a formulary are distinct methods of restricting coverage of outpatient drugs." Pharma. Research & Mfgrs. of Am. v. Meadows, 304 F.3d 1197, 1201 (11th Cir. 2002) (Florida statute adopting a "preferred drug formulary" creates a preferred drug list, not a formulary, because the state would not meet the statutory criteria for a Medicaid formulary).

**C. Relators' Allegations**

Relators' Fourth Amended Complaint ("4AC") contained a section titled "Wooing Medicaid P&T Committee members," Dkt. 114 at ¶¶ 281-89, that alleged that SPI targeted P&T committee members for off-label messages and kickbacks out of "fear that a favorable position on a preferred drug list would be lost or in the hope that an inferior position would be reversed." Id. ¶ 282. The Court's motion-to-dismiss ruling held that these allegations, "[t]aken together" with "the allegations about problems with the DrugDex listings" plausibly alleged that SPI had influenced which drugs were included on state PDLs and formularies.

After Relators filed their 5AC,[3] SPI moved to dismiss these allegations and highlighted certain deficiencies in Relators' allegations about P&T committees that had not been raised in its earlier motion. Dkt. 159, Mem. in Supp. Motion to Dismiss at 23-24. SPI pointed out that PDLs

[3] Relators were granted leave to amend the 4AC with respect to other allegations the Court had dismissed without prejudice. See Dkt. 153 at 131 ("[T]he court believes that justice requires that it provide Relators with an opportunity to re-plead the claims that it has dismissed without prejudice and *only* those claims. No additional claims shall be added.") (emphasis in original). Notably, despite this admonition, Relators added passing mentions of "DUR Boards" to the background section of their 5AC. Compare Dkt. 154, 5AC at ¶¶ 39, 41 with Dkt. 114, 4AC at 36-38. Relators did not make any allegations about any conduct involving any state's DUR Board or its members. Thus, any argument Relators raise today concerning DUR Boards is not properly before the Court.

do not affect Medicaid coverage and that few states had used PDLs during much of the relevant time period and, of those, even fewer had included SPI's drugs. The Court declined to address these arguments in the context of a motion to dismiss and instead invited SPI to make these arguments on summary judgment. Dkt. 173, Order at 9.

**D. PDLs by State during the Relevant Time[4]**

After extensive investigation by SPI, third-party discovery by Relators, and discussions between the parties concerning the state of the record, the uncontroverted evidence concerning Relators' P&T-committee-influence theory boils down to few simple propositions:

- Relators "no longer assert" their P&T-committee-influence theory for every state, or every drug, throughout the Relevant Time.
- In the states where Relators continue to assert their theory, Luvox was not preferred on any state's PDL.
- Of the states where Relators continue to assert their theory, only 14 states listed Aceon or AndroGel as preferred on PDLs, and each of those listings applied only for part of the Relevant Time, as set forth in table below.

| State | Aceon listed as preferred | AndroGel listed as preferred |
|---|---|---|
| Alabama | Dec. 1, 2004-Dec. 31, 2007 | No |
| Connecticut | May 1, 2005-Mar. 31, 2007 | No |
| Delaware | Oct. 27, 2006-Dec. 31, 2007 | Oct. 6, 2006-Dec. 31, 2007 |
| Florida | Oct. 27, 2004-July 5, 2005<br>Mar. 17, 2006-Mar. 31, 2007 | Oct. 27, 2004-Nov. 8, 2005<br>Mar. 17, 2006-Dec.31, 2007 |
| Idaho | Oct. 1, 2006-Dec. 31, 2007 | No |
| Illinois | Oct. 31, 2003-Oct. 7, 2004 | No |
| Iowa | Dec. 23, 2004-Jan. 15, 2006 | No |
| Louisiana | Oct. 1, 2004-Oct. 31, 2005<br>Oct. 1, 2006-Sept. 30, 2007 | Oct. 1, 2006-Dec. 31, 2007 |
| Maryland | Dec. 3, 2003-Sept. 15, 2005<br>Sept. 27, 2006-Aug. 8, 2007 | Sept. 27, 2006-Dec. 31, 2007 |
| Pennsylvania | No | May 1, 2007-Dec. 31, 2007 |

[4] In entering a protective order for SPI, the Court held that the well-pled allegations of the 5AC did not extend beyond December 31, 2007. Dkt. 191 at 13. SPI thus uses the term "Relevant Time" in this motion to refer to that time period—i.e., up until December 31, 2007.

| State | Aceon listed as preferred | AndroGel listed as preferred |
|---|---|---|
| South Carolina | May 19, 2004-Dec. 14, 2005 | No. |
| Texas | No | May 25, 2006-Dec. 31, 2007 |
| West Virginia | June 1, 2005-Oct. 2, 2005<br>Oct. 2, 2006-Sept. 30, 2007 | Oct. 2, 2006-Dec. 31, 2007 |
| Wisconsin | No | Oct. 1, 2006-Dec. 31, 2007 |

The following state-by-state list summarizes the PDL evidence in the record as to each of the three SPI drugs at issue and identifies the states and drugs as to which Relators "no longer assert claims based on the 'P&T Committee influence' theory." Dkt. 286, Relators' Amended Response at 3 (Aug. 29, 2014).[5]

Alabama. The only drug at issue that was listed as preferred on an Alabama PDL during the Relevant Time is Aceon, which was preferred from December 1, 2004 through December 31, 2007. Ex. 8, PDL Chart; Exs. 11-25, Alabama PDLs.

Alaska. Relators "no longer assert" this theory as to Aceon and AndroGel. Dkt. 286 at 3. Alaska did not list Luvox as preferred (which Alaska calls "not requiring justification") during the Relevant Time. Ex. 8, PDL Chart; Exs. 26-33, Alaska PDLs.

Arkansas. Arkansas did not implement a PDL until 2005, and no PDLs are available after that date during the Relevant Time because Arkansas does not maintain archived copies of PDLs. Ex. 626 (email correspondence from Suzeet.Bridges@arkansas.gov stating "our PDL did not start until 2005" and "we do not retain copies of the old lists").

[5] During the meet and confer process in connection with SPI's prior motion for partial summary judgment, Relators withdrew their evidentiary objections to most of SPI's previously submitted PDL exhibits. Dkt. 284. To the extent that Relators reassert evidentiary objections to the remaining PDL exhibits at this stage, after the completion of discovery on Medicaid issues, SPI submits that in addition to being unfounded, those objections are now immaterial. Relators have produced no contrary evidence and, as such, they cannot prove their theory in those states.

Arizona. Relators "no longer assert" this theory as to any of the three drugs at issue. Dkt. 286 at 3.

California. None of the three drugs at issue are listed as preferred on California's PDLs from the Relevant Time. Ex. 8, PDL Chart; Exs. 34-44, California PDLs.[6]

Colorado. Relators "no longer assert" this theory as to Aceon. Dkt. 286 at 3. Colorado did not implement a PDL during the Relevant Time. Ex. 640 at 6, Colorado PDL Program Annual Report, Jan. 1, 2008 – Dec. 31, 2008 (indicating Colorado's first PDL was effective Feb. 1, 2008).

Connecticut. The only drug at issue listed as preferred on a Connecticut PDL during the Relevant Time is Aceon, which was preferred from May 1, 2005 through March 31, 2007. Ex. 8, PDL Chart; Exs. 45-56, Connecticut PDLs.

Delaware. The only drugs at issue listed as preferred on a Delaware PDL during the Relevant Time are AndroGel, which was listed as preferred from October 6, 2006 through December 31, 2007, and Aceon, which was listed as preferred from October 27, 2006 until December 31, 2007. Ex. 8, PDL Chart; Exs. 57-61, Delaware PDLs.

District of Columbia. Relators "no longer assert" this theory as to Aceon. Dkt. 286 at 3. The District of Columbia did not list AndroGel or Luvox as preferred on a PDL during the Relevant Time. Ex. 8, PDL Chart; Exs. 62-66, District of Columbia PDLs.

Florida. The only drugs at issue listed as preferred on a Florida PDL during the Relevant Time are AndroGel, which was listed as preferred from October 27, 2004 through November 8, 2005 and from March 17, 2006 through December 31, 2007, and Aceon, which was listed as

[6] These PDLs were obtained by SPI from California; Relators previously objected to these PDLs but have not identified any additional PDLs in the documents that California produced to Relators. Without these PDLs, Relators will be left with no PDLs from California in the record.

preferred from October 27, 2004 through July 5, 2005 and from March 17, 2006 through March 31, 2007. Ex. 8, PDL Chart; Exs. 67-85Y, Florida PDLs.

Georgia. Relators "no longer assert" this theory as to AndroGel. Dkt. 286 at 3. Georgia did not list Aceon or Luvox as preferred on a PDL during the Relevant Time. Ex. 8, PDL Chart; Exs. 86-110MM, Georgia PDLs.

Hawaii. None of the three drugs at issue are listed as preferred on Hawaii's PDLs from the Relevant Time. Ex. 8, PDL Chart; Exs. 111-115, Hawaii PDLs. [7]

Idaho. Relators "no longer assert" this theory as to AndroGel. Dkt. 286 at 3. Idaho did not list Luvox as preferred on a PDL during the Relevant Time. Ex. 8, PDL Chart; Exs. 116-127, Idaho PDLs. Idaho listed Aceon as preferred on a PDL from October 1, 2006 to December 31, 2007. Id.

Illinois. Relators "no longer assert" this theory as to AndroGel. Dkt. 286 at 3. Illinois did not list Luvox as preferred on a PDL during the Relevant Time. Ex. 8, PDL Chart; Exs. 128-177E, Illinois PDLs. Illinois listed Aceon as preferred on a PDL from October 31, 2003 through October 7, 2004. Id.

Indiana. Relators "no longer assert" this theory as to Aceon. Dkt. 286 at 3. Indiana did not list AndroGel or Luvox as preferred on any of the available PDLs during the Relevant Time. Ex. 8, PDL Chart; Exs. 178-192, Indiana PDLs. Indiana's archives for its PDLs begin in 2006. See The Indiana Health Coverage Program, Preferred Drug List, available at https://inm.providerportal.catamaranrx.com/providerportal/faces/PreLogin.jsp (links for Indiana PDLs for 2006 to 2013). Indiana provided SPI with additional PDLs predating 2006 in response

[7] These PDLs were obtained by SPI from Hawaii; Relators previously objected to these PDLs but did not issue a subpoena to Hawaii seeking PDLs or other documents and have not produced any documents that they received from Hawaii. Without these PDLs, Relators will be left with no PDLs from Hawaii in the record.

to a request for earlier PDLs. Ex. 627 (email correspondence showing that six PDLs from 2005 and one from 2003 provided in response to request submitted to PDL@ffsa.in.gov for Indiana PDLs "are only ones available prior to 2006") .

Iowa. Relators "no longer assert" this theory as to AndroGel. Dkt. 286 at 3. Iowa did not list Luvox as preferred on a PDL during the Relevant Time. Ex. 8, PDL Chart; Exs. 193-205, Iowa PDLs. Iowa listed Aceon as preferred on a PDL from December 23, 2004 through January 15, 2006. Id.

Kansas. None of the three drugs at issue were listed as preferred on the only available Kansas PDL from the Relevant Time. Ex. 8, PDL Chart; Ex. 206, Kansas PDL. Archive records for Kansas are not available prior to 2007. Ex. 628A-628B (email correspondence from Michael G. Smith, Associate Chief Counsel, Health Care Finance, Kansas Dept. of Health and Environment at MSmith@kdheks.gov attaching one PDL from 2007 and seven PDLs from 2008 in response to Kansas Open Records Act request and stating "[t]he State no longer has in its files any of the requested records that predate the May 23, 2007 file attached to this email").[8]

Kentucky. None of the three drugs at issue were listed as preferred on Kentucky's PDLs from the Relevant Time. *See* Ex. 8, PDL Chart; Exs. 207-223, Kentucky PDLs.

Louisiana. The only drugs at issue that were listed as preferred on a Louisiana PDL during the Relevant Time are AndroGel, which was listed as preferred from October 1, 2006 until December 31, 2007, and Aceon, which was listed as preferred from October 1, 2004 to October 31, 2005 and from October 1, 2006 to September 30, 2007. Ex. 8, PDL Chart; Exs. 224-233, Louisiana PDLs.

[8] This PDL was obtained by SPI from Kansas; Relators previously objected to this PDL but did not issue a subpoena to Kansas seeking PDLs or other documents and have not produced any documents that they received from Kansas. Without this PDL, Relators will be left with no PDLs from Kansas in the record.

Maine. Relators "no longer assert" this theory as to Aceon and AndroGel. Dkt. 286 at 3. Maine did not list Luvox as preferred on a PDL during the Relevant Time. Ex. 8, PDL Chart; Exs. 234-241, Maine PDLs.[9]

Maryland. The only drugs at issue that were listed as preferred on a Maryland PDL during the Relevant Time are AndroGel, which was listed as preferred from September 27, 2006 to December 31, 2007, and Aceon, which was listed as preferred from December 3, 2003 to September 15, 2005 and from September 27, 2006 to August 8, 2007. Ex. 8, PDL Chart; Exs. 242-250, Maryland PDLs.

Massachusetts. Relators "no longer assert" this theory as to Aceon and AndroGel. Dkt. 286 at 3. Massachusetts did not list Luvox as preferred on a PDL during the Relevant Time. Ex. 8, PDL Chart; Exs. 251-281B, Massachusetts PDLs.

Michigan. Relators "no longer assert" this theory as to Aceon. Dkt. 286 at 3. Michigan did not list AndroGel or Luvox as preferred on a PDL during the Relevant Time. Ex. 8, PDL Chart; Exs. 282-300I, Michigan PDLs.

Minnesota. Relators "no longer assert" this theory as to Aceon. Dkt. 286 at 3. Minnesota did not list AndroGel or Luvox as preferred on any available PDL during the Relevant Time. Ex. 8, PDL Chart; Exs. 301-323C, Minnesota PDLs. Minnesota implemented a PDL in 2002, but has no archived records prior to July 2004. Ex. 632, (email correspondence from Ken Parsons, Staff Attorney at Minnesota Department of Human Services stating "the earliest source of information on the PDL's was: 7/20/04").

[9] These PDLs were obtained by SPI from Maine; Relators previously objected to these PDLs but did not issue a subpoena to Maine seeking PDLs or other documents and have not produced any documents that they received from Maine. Without these PDLs, Relators will be left with no PDLs from Maine in the record.

Mississippi. None of the three drugs at issue were listed as preferred on a Mississippi PDL during the Relevant Time. Ex. 8, PDL Chart; Exs. 324-333C, Mississippi PDLs.

Missouri. None of the three drugs at issue were listed as preferred on a Missouri PDL during the Relevant Time. *See* Ex. 8, PDL Chart; Exs. 334-337, Missouri PDLs.

Montana. Relators "no longer assert" this theory as to Aceon and AndroGel. Dkt. 286 at 3. Montana did not list Luvox as preferred on a PDL during the Relevant Time. Ex. 8, PDL Chart; Exs. 338-349, Montana PDLs.

Nebraska. Relators "no longer assert" this theory as to Aceon in this state. Dkt. 286, Relators' Amended Response at 3 (Aug. 29, 2014). Moreover, Nebraska did not implement a PDL during the Relevant Time. Ex. 641 at 1, Neb. Leg. Bill 83 (establishing PDL, approved by governor on Apr. 17, 2008).

Nevada. Relators "no longer assert" this theory as to any of the three drugs at issue. Dkt. 286 at 3.

New Hampshire. Relators "no longer assert" this theory as to Aceon and AndroGel. Dkt. 286 at 3. New Hampshire did not list Luvox as preferred on any of the available PDLs during the Relevant Time. Ex. 8, PDL Chart; Exs. 372-379, New Hampshire PDLs.

New Jersey. There is no evidence that New Jersey used a PDL during the Relevant Time. There is no reference to a Medicaid PDL in New Jersey's statutes or administrative code. On or about May 16, 2013, Relators served a subpoena on the New Jersey Department of Human Services seeking documents related to a state P&T committee. Ex. 649 (Notice of Intent to Issue Subpoena Duces Tecum to New Jersey Department of Human Services). Relators have not identified any PDLs produced by New Jersey in response.

New Mexico. Relators "no longer assert" this theory as to Aceon and AndroGel. Dkt. 286 at 3. No New Mexico PDLs are available during the Relevant Time because New Mexico does not have archived copies of PDLs. Ex. 633 (email correspondence from Betina Gonzales McCracken, Public Records Custodian at betina.mccracken@state.nm.us stating agency was "unable to locate any PDL copies").

New York. None of the three drugs at issue were listed as preferred on a New York PDL during the Relevant Time. Ex. 8, PDL Chart; Exs. 380-384, New York PDLs.[10]

North Carolina. North Carolina did not have a PDL during the Relevant Time. Ex. 642 at 108, N.C. Sess. Law 2009-451 (establishing PDL program as part of 2009 appropriations act).

North Dakota. Relators "no longer assert" this theory as to Aceon and AndroGel. Dkt. 286 at 3. North Dakota did not have a PDL during the Relevant Time. Ex. 634 (email correspondence from Brendan Joyce at North Dakota Medicaid stating that North Dakota still does not use a PDL).

Ohio. Relators "no longer assert" this theory as to Aceon. Dkt. 286 at 3. Ohio did not list AndroGel or Luvox as preferred during the Relevant Time. Ex. 8, PDL Chart; Exs. 385-391L, Ohio PDLs.[11]

---

[10] These PDLs were obtained by SPI from New York; Relators previously objected to these PDLs but did not identify any additional PDLs from New York from the Relevant Time. Without these PDLs, Relators will be left with no PDLs from New York in the record.

[11] Relators have informed SPI that they object to four Ohio PDL exhibits that SPI previously submitted. Three of those exhibits—Exs. 385, 386, and 390—are an exact match to PDLs that Relators obtained from the applicable Ohio state agency and produced to SPI. Compare Exs. 385-386 (two copies of 10/1/2007 Ohio PDL submitted by SPI) with Ex. 391M (10/1/2007 Ohio PDL obtained from Relators' Ohio state production); compare Ex. 390 (8/13/2003 Ohio PDL submitted by SPI) with Ex. 391N (8/13/2003 Ohio PDL obtained from Relators' Ohio state production). For the fourth objected-to Ohio PDL exhibit, Ex. 391, Relators' Ohio state production includes a PDL with the same date, the same listing of preferred

Oklahoma. Oklahoma did not use a PDL during the Relevant Time. Ex. 629 (email correspondence from Carolyn.Berry-Greer@okhca.org stating "Oklahoma Medicaid does not have a Preferred Drug List.")[12]

Oregon. Relators "no longer assert" this theory as to Aceon. Dkt. 286 at 3. Oregon did not list AndroGel or Luvox as preferred on a PDL during the Relevant Time. Ex. 8, PDL Chart; Exs. 405A-439, Oregon PDLs.

Pennsylvania. The only drug at issue that Pennsylvania listed as preferred on a PDL during the Relevant Period is AndroGel, which was preferred from May 1, 2007 to December 31, 2007. *See* Ex. 8, PDL Chart; Exs. 440-449A, Pennsylvania PDLs.

Rhode Island. Relators "no longer assert" this theory as to Aceon. Dkt. 286 at 3. No PDLs are available during the Relevant Time because Rhode Island does not have copies of PDLs prior to 2009. Ex. 635 (email correspondence from JDellaPosta@ohhs.ri.gov forwarding email from Ann L. Bennett, Pharmacy Team, RI Medicaid Account, confirming that 2009-2012 are "all of the old PDL files that I have").

South Carolina. The only drug at issue that South Carolina listed as preferred during the Relevant Time is Aceon, which was preferred from May 19, 2004 to December 14, 2005. Ex. 8, PDL Chart; Exs. 450-463, South Carolina PDLs.

---

drugs, and the same agency markings, as the objected-to PDL. Compare Ex. 391 (3/10/2003 Ohio PDL submitted by SPI) with Ex. 391O (3/10/2003 Ohio PDL located in Relators' Ohio state production). The only substantive difference between these documents is that the version in Relators' Ohio state production lists both the preferred drugs and those requiring prior authorization, whereas SPI's Ex. 391 only lists the preferred drugs. Id.

[12] The email correspondence refers to a "multi-tiered step therapy prior authorization program called the Product Based Prior Authorization," which the email indicates can be found at http://www.okhca.org/providers.aspx?id=1218. This website states that Oklahoma's DUR Board—not the state's P&T committee—developed this prior authorization program. In any event, the available archive lists on the website only date back to 2009.

South Dakota. Relators "no longer assert" this theory as to Aceon and AndroGel. Dkt. 286 at 3. South Dakota did not implement a PDL during the Relevant Time. Ex. 650, South Dakota PDL Request for Information (Feb. 10, 2012) at 2, 5-6 ("South Dakota is one of the few remaining states that has not implemented a Medicaid Preferred Drug List"). And although it used a prior authorization list developed by its P&T committee, id. at 5-6, no archived lists are available. Ex. 636 (email correspondence from Mike.Jockheck@state.sd.us confirming no archive copies of list are available on-line or in hard copy).

Tennessee. Relators "no longer assert" this theory as to Aceon. Dkt. 286 at 3. The available PDLs for Tennessee do not list AndroGel or Luvox as preferred for the Relevant Time. Ex. 8, PDL Chart; Exs. 464-486, Tennessee PDLs. Tennessee has very limited and incomplete archive records of its PDL prior to April 2006. Ex. 637 (email correspondence from angie.williams.tn.gov confirming that partial PDLs dated 1/1/04, 8/1/05, 9/1/05, 10/1/05, 11/1/05, and 12/1/05 are "everything TennCare has available to produce" prior to 2006).

Texas. The only drug at issue that Texas listed as preferred on a PDL during the Relevant Time is AndroGel, which was listed as preferred from May 25, 2006 to December 31, 2007. Ex. 8, PDL Chart; Exs. 607-625, Texas PDLs.

Utah. Relators "no longer assert" this theory as to Aceon. Dkt. 286 at 3. The only PDL that Utah had during the Relevant Time was implemented in 2007, and it applied only to statins and Proton Pump Inhibitors. Ex. 643A, Utah State Plan Attachment 3.1-A, Attachment #12a(6) (providing "Division shall implement a [PDL] for select therapeutic drug classes beginning August 1, 2007"); Ex. 643B at 2, State of Utah Medicaid Preferred Drug List report (listing "PPI" and "High Potency Statin" as only PDL classes implemented in 2007).

Vermont. Relators "no longer assert" this theory as to Aceon and AndroGel. Dkt. 286 at 3. Vermont did not list Luvox as preferred on a PDL during the Relevant Time. Ex. 8, PDL Chart; Exs. 487-514, Vermont PDLs.

Virginia. None of the drugs at issue were listed as preferred on Virginia's PDL during the Relevant Time. Ex. 8, PDL Chart; Exs. 515-522C, Virginia PDLs.

Washington. Relators "no longer assert" this theory as to Aceon. Dkt. 286 at 3. The available PDLs for Washington did not list AndroGel or Luvox as preferred during the Relevant Time. Ex. 8, PDL Chart; Exs. 523-530C, Washington PDLs.

West Virginia. The only drugs at issue that West Virginia listed as preferred during the Relevant Time are AndroGel, which was listed as preferred from October 2, 2006 to December 31, 2007, and Aceon, which was listed as preferred from June 1, 2005 to October 2, 2005 and from October 2, 2006 to September 30, 2007. Ex. 8, PDL Chart; Exs. 531-563, West Virginia PDLs.

Wisconsin. The only drug at issue that Wisconsin listed as preferred on a PDL during the Relevant Time is AndroGel, which was listed as preferred from October 1, 2006 to December 31, 2007. Ex. 8, PDL Chart; Exs. 564-599, Wisconsin PDLs.

Wyoming. Relators "no longer assert" this theory as to Aceon and AndroGel. Dkt. 286 at 3. The available PDLs for Wyoming do not list Luvox as preferred during the Relevant Time. Ex. 8, PDL Chart; Exs. 600-604, Wyoming PDLs.[13] Archive records for Wyoming are not available prior to 2006. *See* Ex. 638 (email correspondence from Tate Nuckols, JD, Security Officer, Wyoming Department of Health at tate.nuckols@wyo.gov attaching Wyoming PDLs for

[13] These PDLs were obtained by SPI from Wyoming; Relators previously objected to these PDLs but did not issue a subpoena to Wyoming seeking PDLs or other documents and have not produced any documents that they received from Wyoming. Without these PDLs, Relators will be left with no PDLs from Wyoming in the record.

2006-2008 and stating "[t]his is as far back as the lists go").

**E. No State Has Implemented A Medicaid Formulary.**

To establish a Medicaid formulary, a state must—as the 5AC acknowledged—satisfy specific requirements. 5AC ¶¶ 39-40. Based on SPI's review of publicly available CMS-approved Medicaid State Plans, no state has implemented a formulary. See, e.g., Ex. 644, Excerpt of Medicaid State Plan for Texas, Appendix 1 to Attachment 3.1-A, §12a. Prescribed Drugs (describing Texas's P&T Committee and use of a PDL); Ex. 645, Excerpt of Medicaid State Plan for Tennessee, Attachment 3.1.A.I, § 12.a(3), (10) (describing prior approval system and implementation of PDL). Since no state has established a Medicaid formulary, it logically follows that none of the drugs at issue are included on one.[14]

**STATEMENT OF ISSUE AND STANDARD OF REVIEW**

The issue before the Court is whether SPI is entitled to summary judgment on some or all of Relators' P&T-committee-influence theory. Summary judgment on a claim or part of a claim is appropriate if there is no genuine dispute as to any material fact. See Fed. R. Civ. P. 56(a). Material facts are those which "might affect the outcome of the suit under governing law." Rodriguez v. Township of Holiday Lakes, 866 F. Supp. 1012, 1016 (S.D. Tex. 1994) (citing Anderson v. Liberty Lobby, 477 U.S. 242, 248 (1986)). "[A] fact is genuinely in dispute only if a reasonable jury could return a verdict for the non-moving party." Fordoche, Inc. v. Texaco, Inc., 463 F.3d 388, 392 (5th Cir. 2006).

[14] The only state that has ever requested that CMS approve a Medicaid formulary is Washington State, which made the request in 2012. CMS did not accept that State Plan Amendment, see Ex. 646, Letter from CMS to Doug Porter, Washington Health Care Authority (Sept. 25, 2012), and Washington State withdrew its request in 2013. See Ex. 647, Letter from Washington Health Care Authority to Interested Parties (Apr. 2, 2013) (stating that "HCA will withdraw its Centers for Medicare and Medicaid Services State Plan Amendment and cease development and implementation of a Medicaid FFS formulary, effective immediately").

A defendant moving for summary judgment may satisfy its burden by submitting evidence that negates a material element of the plaintiff's claim or by showing that no evidence supports an essential element of the plaintiff's claim. United States v. Medica-Rents Co., 285 F. Supp. 2d 742, 768 (N.D. Tex. 2003) (citing Celotex Corp. v. Catrett, 477 U.S. 317 (1986)). To avoid summary judgment, Relators "must submit or identify evidence in the record to show the existence of a genuine issue of material fact as to each element of the[ir] cause of action." Malacara v. Garber, 353 F.3d 393, 404 (5th Cir. 2003).

## SUMMARY OF THE ARGUMENT

Relators alleged that SPI improperly influenced state P&T Committee members to obtain preferred listings on PDLs and inclusion in Medicaid formularies, and thereby improperly caused states to make claims for its drugs reimbursable when they would not otherwise have been. SPI is entitled to summary judgment on this theory as a matter of both law and fact. First, the law: even if PDL evidence showed SPI's drugs had received a "preferred" status for some periods of time, SPI would be entitled to summary judgment as a matter of law because preferred status on a PDL does not expand the uses or indications for which the drug is covered by Medicaid. PDLs are a mechanism for a state to require prior authorization of certain drugs, and nothing more. They do not alter a state's obligation under the Medicaid statute to pay claims for "medically accepted indications" of these drugs.

Second, the evidence: The available PDL evidence from all 50 states and the District of Columbia shows that during the Relevant Time: (1) Aceon, AndroGel, and Luvox lacked "preferred" status in most states that had implemented a PDL; (2) a number of states had not implemented a PDL: and (3) records supporting Relators' theory for a number of other states simply are not available. As a matter of fact, therefore, SPI is entitled to summary judgment on Relators' P&T-committee-influence theory as follows: It is entitled to summary judgment as to

Luvox for all 50 states and the District of Columbia for the entire Relevant Time. It is entitled to summary judgment as to AndroGel for 42 states and the District of Columbia for the entire Relevant Time and for some time periods in the remaining 8 states. And it is entitled to summary judgment as to Aceon for 39 states and the District of Columbia for the entire relevant time period and for some time periods in the remaining 11 states.

In addition, there is no evidence that any SPI drug was placed on a Medicaid formulary, because although statutorily authorized, no state has implemented a Medicaid formulary. See 42 U.S.C. § 1396r-8(d)(4). See 5AC ¶¶ 39-40 (describing the requirements for this formulary).

For each of the aforementioned reasons, there is no genuine issue of material fact as to whether SPI caused false claims to be submitted by wooing state P&T Committees to include particular drugs on a PDL or Medicaid formulary.

## ARGUMENT

## SPI IS ENTITLED TO SUMMARY JUDGMENT ON RELATORS' P&T-COMMITTEE-INFLUENCE THEORY.

### A. Summary judgment is warranted because placement on a PDL determines only whether prior authorization is required and does not make particular uses of that drug reimbursable.

Relators' legal theory would fail regardless of what the evidence showed as to whether states had listed SPI's drugs as preferred on PDLs. That is because a drug prescribed for a medically accepted indication is reimbursable by state Medicaid programs, irrespective of any PDL listing. PDL listings only determine whether a drug is, or is not, subject to a prior authorization requirement. Put simply, the Medicaid statute mandates that all drugs—whether preferred or not—be covered for medically accepted indications (except in limited circumstances that do not apply here). See 42 U.S.C. § 1396r-8(d)(1). Relators' theory that SPI "duped" states into listing its drugs as "preferred," and thereby somehow caused the state to pay for claims it

would not have otherwise covered, is inconsistent with the applicable statutory and regulatory framework.

At a threshold level, Relators seem to confuse the concept of a PDL with the entirely distinct concept of a Medicaid "formulary." As discussed above, Medicaid authorizes states to exclude coverage of drugs for certain uses or populations, as long as the state complies with the requirements for establishing a formulary. 42 U.S.C. § 1396r-8(d)(4). This sort of formulary is commonly encountered in the private insurance market. PDLs, however, are an entirely distinct mechanism that a state may utilize in its Medicaid program. PDLs, unlike formularies, are not about excluding drugs from *coverage*. Listing a drug on a PDL as preferred does not an expand the "medically indicated" uses of that drug that Medicaid requires the state to cover. Rather, when a patient seeks prior authorization for a medically indicated use, the state has to pay for it. As one State Plan explains, for example:

> Drugs added to the Preferred Drug List (PDL) are based on recommendations submitted by the Pharmacy and Therapeutics Advisory Committee to the Commissioner of the Kentucky Department for Medicaid Services for approval. Drugs requiring prior authorization must follow the process listed below. Approval of prior authorization is based on FDA-approved indications or a medically accepted indication documented in official compendia or peer-reviewed medical literature.

Ex. 648, Excerpt of Kentucky Medicaid State Plan, Attachment 3.1-A § 12(a)(1) (emphasis added).

The language in this state plan is unsurprising; the Medicaid statute, after all, says that states that provide prescription drug coverage generally must reimburse prescriptions of all "covered outpatient drug[s]" for all "medically accepted indication[s]," and defines "medically accepted indications" to include FDA-approved and compendia-supported indications. 42 U.S.C. § 1396r-8(k)(6); 42 U.S.C. § 1396r-8(d)(1)(B)(i). PDLs are a way for a state to encourage drug manufacturers to enter into supplemental rebate agreements with states and

thereby reduce the cost of that manufacturer's drugs for the state's Medicaid program. While the exact contours of the lists vary from state to state, PDLs generally separate drugs (or categories of drugs) into two groupings: those that do, and those that do not, require prior authorization. The listing of a drug as preferred on a PDL does not render a drug reimbursable for non-medically accepted indications (i.e., an off-label use lacking the requisite compendia support).

Thus, the statutory and regulatory framework entitles SPI to summary judgment on Relators' P&T-committee-influence theory. Relators' contention that SPI's "wooing" or "targeting" of state P&T committee members with off-label marketing somehow expanded the state's coverage for SPI's drugs by getting the drugs listed on PDLs has no basis in the applicable law. A PDL listing does not affect in any way the determination of what the medically accepted indications are for a drug, and as a result, PDL listings cannot—as a matter of law—transform a non-reimbursable use into a reimbursable one.[15]

**B. Summary judgment is warranted on Relators' theory as to all of the states and drugs for which Relators "no longer assert" it.**

Setting aside the legal infirmity in Relators' theory, Relators have stated that they "no longer assert claims based on the 'P&T Committee influence' theory as to the following States and drugs:"

[15] SPI anticipates that Relators will not provide any substantive response to this argument. Instead, Relators are likely to declare that the Court previously rejected this argument and refer to the Court's orders on the plausibility of their allegations. Relators' assertion, if made, will be incorrect. The Court has not previously addressed, let alone ruled on, whether Relators are conflating PDLs with closed Medicaid formularies. Nor has it addressed or ruled on Relators lack of evidence that being listed as preferred on a PDL expanded the list of reimbursable uses for a drug to include uses that would have otherwise been non-reimbursable. Nor has it addressed whether claims for indisputably reimbursable uses are "false claims" because a state might have asked for additional documentation before paying them. At most, the Court's motion-to-dismiss ruling found that Relators had plausibly alleged that SPI defrauded state P&T committee members, without making any ruling on the issues listed above. And in any event, the Court specifically informed both parties that SPI was "free to reassert its arguments at the summary judgment stage." Dkt. 173 at 9.

A. Luvox: Arizona and Nevada;

B. Aceon: Alaska, Arizona, Colorado, DC, Indiana, Maine, Massachusetts, Michigan, Minnesota, Montana, Nebraska, Nevada, New Hampshire, New Mexico, North Dakota, Ohio, Oregon, Rhode Island, South Dakota, Tennessee, Utah, Vermont, Washington, and Wyoming; and

C. Androgel: Arizona, Alaska, Georgia, Idaho, Illinois, Iowa, Maine, Massachusetts, Montana, Nevada, New Hampshire, New Mexico, North Dakota, South Dakota, Vermont, and Wyoming.

Dkt. 286 at 3. As a result, it is undisputed that SPI is entitled to summary judgment in its favor as to these drugs and states.

**C. Summary judgment is warranted on Relators' theory as to States that had not implemented a PDL during the Relevant Time.**

To avoid dismissal at the pleading stage, Relators theorized that SPI rendered claims for off-label uses of the three drugs reimbursable when they otherwise would not have been by deceiving or bribing (largely unidentified) state P&T committee members across the country into listing those drugs as "preferred" on state PDLs. Prevailing on such a theory would require, as an initial matter, evidence showing that the drugs actually were listed as preferred on a state's PDL. In seven states, however, the evidence shows that the states did not have a PDL at all during the relevant time period. Those states are: Colorado, Nebraska, New Jersey, North Carolina, Oklahoma, North Dakota, and South Dakota. See Exs. 629, 634, 640-42, 650; see also supra at 17 (New Jersey). As a result and without further analysis necessary, SPI is entitled to summary judgment on Relators' P&T-committee-influence theory as to these seven states.

**D. Summary judgment is also warranted on Relators' theory to the extent that each state's PDL did not list Aceon, AndroGel, or Luvox as "preferred."**

Even where PDL records exist, those records undermine the factual basis for Relators' P&T-committee-influence theory. That theory fails as a matter of fact as to each state and each time period in which SPI's drugs were not designated as preferred. And that is to say, it fails in

large part. For twenty-four states and the District of Columbia, the available records show that none of the drugs for which Relators continue to assert their theory obtained preferred status at any point during the Relevant Time. The twenty-five jurisdictions are: Alaska, California, the District of Columbia, Georgia, Hawaii, Indiana, Kansas, Kentucky, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, New Hampshire, New York, Ohio, Oregon, Tennessee, Utah, Vermont, Virginia, Washington, and Wyoming. Ex. 8, PDL Chart; Exs. 26-44, 62-66, 86-115, 178-192, 206-223, 234-241, 251-349, 372-391L, 405A-439, 464-486, 487-530C, 600-604, 643A-B , PDLs for corresponding states. For these states, Relators lack any evidence that could substantiate their claim that improper "wooing" by SPI caused P&T committees to list the drugs as preferred on a state PDL. And the lack of preferred status, in turn, negates a material element of Relators' theory that the drugs' preferred status on a PDL resulted in otherwise non-reimbursable claims being paid. SPI is entitled to summary judgment as to Relators' PDL theory for these twenty-five jurisdictions.

Ultimately, there are only eight states where Relators are asserting this theory and there is evidence that AndroGel was listed as preferred at any relevant point: Delaware, Florida, Louisiana, Maryland, Pennsylvania, Texas, West Virginia, and Wisconsin. And there are only eleven states where Relators are asserting this theory and there is evidence that Aceon was listed as preferred at any relevant point: Alabama, Connecticut, Delaware, Florida, Idaho, Illinois, Iowa, Louisiana, Maryland, South Carolina, and West Virginia. And even in these states, the drugs were only listed as preferred for a small portion of the Relevant Time, often no more than a single year or two at the most. See supra at 11-12 (chart of time periods).

SPI is entitled to summary judgment as to all states, and all time periods, in which its drugs were not listed as preferred on a state's PDL. Relators have a "complete failure of proof

concerning an essential element" as to their PDL theory for the states and time periods in which the evidence shows that the drugs were not listed as preferred. Celotex Corp., 477 U.S. at 322-23. This shortcoming "mandates the entry of summary judgment" for SPI. Id.

**E. Summary judgment is likewise warranted on Relators' theory where there is no evidence that SPI's drugs were listed as "preferred" on a state's PDL during the relevant time period.**

In addition to the states that did not have a PDL, or list the drugs as preferred, eight states lack records of what drugs were listed on their PDLs during the relevant time period. The non-existence of this essential evidence to Relators' PDL theory is fatal to their claims. See Teply v. Mobil Corp., 859 F.2d 375, 379 (5th 1988) (explaining that "the party moving for summary judgment need not disprove its opponent's claim, but need show only that the party who bears the burden of proof has adduced no evidence to support an element essential to its case").

Those eight states are: Arkansas (no archived records), Indiana (limited records before 2006); Kansas (no records before 2007); Minnesota (no archived records until 2004); New Mexico (no archived records), Rhode Island (no archived records from entire Relevant Time), Washington (no archived records until 2007), and Wyoming (no archived records until 2006). See Exs. 530C, 626, 627, 628A-B, 632, 633, 635, 638.[16] For these states and time periods in which there are no records of the state's PDL, there is no evidence that would substantiate a claim that SPI's drugs were listed as preferred on that PDL—let alone that SPI caused them to be so listed, and that this in turn caused claims for off-label uses to be transformed into reimbursable claims. In these states, the absence of evidence showing that SPI's drugs appeared on a PDL is fatal to Relators' theory that SPI somehow improperly induced these states to include SPI's drugs on their PDLs.

[16] In addition, in South Dakota where the state's P&T committee used a different sort of prior authorization program than a PDL, there are no archived records. Ex. 636.

**F. Summary judgment is warranted on Relators' theory as it relates to formularies because no state has implemented a Medicaid formulary.**

As Relators' 5AC notes, a state proposing to adopt a Medicaid formulary must meet particular statutory requirements to do so. 5AC ¶¶ 39, 40 (citing 42 U.S.C. § 1396r-8(d)(4)). Relators lack any evidence that any state met these requirements and implemented a Medicaid formulary during the relevant time period (or since then, for that matter). No state has done so.

Adopting a formulary is a serious matter, because it permits states to exclude medically accepted indications of drugs, which otherwise must be covered. Supra at 9.[17] A state would have to indicate in its State Plan on file with CMS that it had done so, and no state's State Plan indicates that there is a formulary in place. In this context, the name a state adopts for its plan is not dispositive of its status as a feature of the Medicaid program—if a State has not obtained CMS approval to operate a Medicaid formulary, it cannot assert that a formulary bars coverage for a medically accepted use of an FDA-approved drug. See Pharma. Research & Mfgrs. of Am. v. Meadows, 184 F. Supp. 2d 1186 (N.D. Fla. 2001) ("[The Florida statutes], as amended in 2001, do not authorize the creation of a 'formulary' as that term is used in the federal Medicaid law but, instead, allow the establishment of a 'preferred drug list' and a 'prior authorization program' expressly permitted by the federal Medicaid law."), aff'd, 304 F.3d 1197.

No indication exists in any public record that any state has sought to use its P&T Committee to establish such a formulary. Post-dating the Relevant Time, Washington State did request approval to implement a formulary in 2012, but it then withdrew the request in 2013

[17] This type of formulary is referred to a "closed formulary" because it is a "closed" list of drugs a state covers. As CMS's predecessor the Health Care Financing Administration explained, states cannot "us[e] a prior authorization program as a proxy for a closed formulary." 60 Fed. Reg. 48,442, 48,454 (Sept. 19, 1995). And even if a state were to implement a closed formulary (which none have), the state would have to "permit coverage of a drug excluded from the formulary . . . pursuant to a prior authorization program." Id.

before CMS had ruled on it. Exs. 646-647. Since there is no evidence that any state ever adopted a Medicaid formulary, there can be no evidence that SPI's drugs appeared on any state's Medicaid formulary, and SPI is entitled to summary judgment to the extent Relators' theory involves formulary listings.

**G. Relators liability theory is limited to improper influence on P&T Committees affecting listings on formularies and PDLs as pled in their complaint.**

In response to SPI's initial motion seeking partial summary judgment on this theory, Relators argued that "states restrict drugs in a variety of ways, including but not limited to prior authorization, drug utilization review ('DUR'), formularies, and PDLs." Dkt. 286, Relators' Am. Resp. to SPI's MPSJ at 6 (emphasis in original). They then accused SPI of "ignoring" DUR Board controls and other forms of prior authorization because "PDLs represent just one means of administrative control of drug utilization employed by the various states." Id. at 2, 7. SPI did not address those straw men before and need not address them here because the operative complaint contains no allegation—not one—that false claims resulted from improper influence on DUR Boards or any form of prior authorization program other than a PDL or formulary. Relators cannot avoid summary judgment now by seeking, in effect, leave to amend two years after the deadline to do so has passed. Dkt. 193 (scheduling order setting October 17, 2012 as the date amendments to the pleadings were due).

The term DUR Board never appears in the 4AC, which is the complaint the Court evaluated for compliance with the Rule 9(b) and 12(b)(6) pleading standards. After the Court granted Relators leave to amend other partially dismissed claims, Relators added two references to DUR Boards in the background section of the 5AC. But they did not make any claims or allegations about SPI's dealings with DUR Boards. Nor could they have done so, since the order granting Relators' leave to file the 5AC allowed them only "to re-plead the claims that it has

dismissed without prejudice and only those claims." Dkt. 153 at 131 (emphasis in original); id. ("No additional claims shall be added.").

The term "administrative control" never appears in the 4AC or in the 5AC. Nor are there any allegations about any form of administrative control besides PDLs in either complaint. The background section of the 5AC simply states that "states may use prior authorization programs or preferred drug lists to control potential abuses of drug," 5AC ¶ 36 (emphasis added), but Relators allegations about P&T influence do not mention the phrase "prior authorization" or discuss any sort of "administrative control" outside of PDLs. Id. ¶¶ 287-95.

Relators' after-the-fact attempt to shoe-horn a new theory into their 11-year old claims simply cannot serve to resuscitate the theory they actually pled. SPI is entitled to summary judgment on their P&T-committee-influence theory.

**CONCLUSION**

For the foregoing reasons, SPI respectfully requests that the Court grant its motion for partial summary judgment on Relators' P&T-Committee-influence theory as it applies to all remaining federal and state causes of action.

Dated: October 7, 2014

Respectfully submitted,

ABBVIE PRODUCTS, LLC, f/k/a
SOLVAY PHARMACEUTICAL, INC.

By its Attorneys,
HOGAN LOVELLS US LLP

/s/ Bruce D. Oakley

Bruce D. Oakley
Texas Bar No. 15156900
Southern District No. 11824
700 Louisiana Street, Suite 4300
Houston, Texas 77002
Tel.: (713) 632-1420

Fax: (713) 632-1401
Email: bruce.oakley@hoganlovells.com

**ATTORNEY-IN-CHARGE FOR ABBVIE PRODUCTS, LLC, f/k/a SOLVAY PHARMACEUTICAL, INC.**

**Of Counsel:**

Jonathan L. Diesenhaus (pro hac vice)
Jessica L. Ellsworth (pro hac vice)
555 Thirteenth Street, NW
Washington, DC 20004
Tel.: (202) 637-5600
Fax: (202) 637-5910
Email: jonathan.diesenhaus@hoganlovells.com
Email: jessica.ellsworth@hoganlovells.com